# LABORATORY CERTIFICATION STANDARDS REVIEW COUNCIL MEETING MINUTES FROM 2/12/98

#### **Attendance**

Staff: Jack Sullivan, Mike Kvitrud and Alfredo Sotomayor

Council Members: Mary Christie (Chair), Gilbert Williams (Vice-chair), David Kollakowsky, RuthKlee

Marx, Bill Sonzogni, Debbie Cawley, Barb Hill and Russ Janeshek. The absence of Bill

Bruins was previously excused thus all Council members were accounted for.

Guests: Barb Burmeister (SLH), Laura Forst (DATCP), Paul Harris (Davy Labs), Paul Junio

(NET, Inc.), Art Lautenback (Robert E. Lee)

## **Action Item Summary**

• The previous meeting's minutes were accepted.

- The Council suggested that labs which have never been audited be a top priority.
- The Council suggested that a one page closure letter be written instead of a full report if an audit occurred over 2 years ago.
- The Council approved increasing the ASA to \$516 K and using the new formula to calculate fees.
- The Council requested to see the list of ideas for future rule changes.
- The Council will write a letter to the Department stating its concern about the lack of internal communication among Department's different programs. The program also committed to bringing this concern to the Department's attention.
- The Department will begin a legal review of the statute concerning NELAP adoption.

### Agenda Items

- I. Approval of November 13, 1997 Meeting Minutes
  - A. A motion was made by Dr.Sonzogni to accept the November 13, 1997 meeting minutes, it was seconded by Mr. Kollakowsky and the minutes were unanimously accepted.
- II. Laboratory Certification Program Updates
  - A. Consecutive Reference Sample Failures
    - 1. The Department is intending on returning to a stronger enforcement position on laboratories which have consecutive reference sample failures for the same test(s).
    - 2. The Department will issue Notices of Noncompliance NONs) for failing 2 consecutive reference samples and Notices of Violation NOVs) for failing three consecutive reference samples in non-drinking water categories.
    - 3. For SDWA certification (category 18), NOVs will be issued for 2 consecutive reference sample failures.
    - 4. Labs may resolve the NON by submitting corrective actions and passing a reference sample. Labs may resolve the NOV by voluntarily withdrawing certification or registration for the specific test which had the consecutive reference sample failure problem. The test(s) may then be added back to a lab's registration or certification when the problem is corrected by passing two consecutive reference samples and submitting a revised application.
    - 5. Timelines for submitting corrective actions and analyzing the reference samples will be set in the NON letter.
    - 6. Reference or performance evaluation (PE) samples are available from many acceptable providers, two of the providers offer quick turn around PE samples which can be completed within a week.

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- 7. Mr. Kollakowsky suggested that the reference sample providers be listed in the Notices.
- 8. Details of this finalized procedure will be sent to the council members along with the draft minutes of this meeting.

### B. Program Status

- 1. The 2 new central office auditors will be doing unobserved audits next month. Therefore, the number of audits should increase soon.
- 2. The regional auditing program is headed for its goal of 100 audits this year.
- 3. Mr. Kollakowsky asked how many labs have never been audited by the program. The program is still working on this, about 10-15 labs in the program have never been audited. Mr. Kollakowsky suggested that these labs be a top priority since this topic is continually used to criticize the effectiveness of the program.
- 4. The program is mostly caught up on its audit reports. Only one auditor has some audits remaining without written reports. Mr. Sullivan asked the Council how old an audit should be before writing the report would no longer be useful. The program was entertaining not writing reports for audits which were over 3 years old and placing those labs back on the "to be audited" list. The Council suggested that audit reports should not be written if the audit occurred over 2 years ago. However, several members stated that no audit should be left without a written closure letter. Ms. Hill suggested that a one page closure letter including a summary of the lab's status should be sent in lieu of an audit report for those audits which occurred over 2 years ago. Full Council concurrence was obtained.
- 5. The program's goal of the time between an audit and its report is 30 days. Mr. Sullivan asked the Council how much time it has taken other accrediting agencies to produce an audit report. Ms. Hill said it typically takes 30-60 days.

#### C. Budget Report

- 1. A 1999 fiscal year (FY) proposed budget was distributed and explained.
- The program is required to collect fees in advance for administering the program; therefore, it
  is supposed to have a full year's operating expenses at the beginning of the fiscal year. The
  program was very close to having a full year's expenses at the beginning of this fiscal year (FY
  1998).
- 3. The program is now budgeting for a summer intern [\$2 K], NELAC and the Technical Advisory Committee (TAC) [\$5 K] as well as the Oracle database conversion and expenses [\$53 K] in its FY 1999 proposed budget. These items will push the program's total expenses beyond its Approved Spending Authority (ASA) of \$463 K. In order to balance the proposed budget, the program has requested an increase in its ASA to \$516 K through s. 16.515, Wis. Stats. The bulk of this increase is due to the Oracle conversion and will be a one time expense. The Department of Administration (DOA) must approve the 16.515 request before the ASA can be increased. If the ASA is not increased, the program will have to cut items out of the budget.
- 4. **Dr. Sonzogni asked if staff time for NELAP was included in the budget**Extra staff time was not budgeted solely for NELAP, staff would need to shift from their other duties to implement NELAP in Wisconsin (change the rules and statutes).
- 5. Depending on the timing of the current NR 149 rule change, the program may use either the current or the proposed formula for calculating fees. The same amount of money will be collected either way, it will just be distributed slightly different between certified, registered and reciprocity labs.
- 6. Mr. Kollakowsky made a motion to approve increasing the ASA to \$516 K, it was seconded by Mr. Williams and the increase was unanimously approved. Using the new formula to calculate fees this May was also approved in the same motion.

#### D. NR 149 Rule Change

<sup>\*</sup> This information has been updated since the Council meeting.

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- 1. There were no negative or positive comments on changing the fee formula. The workload analysis supported the change which will slightly increase the fees for certified and reciprocity labs, while lowering the fees for registered labs.
- 2. Immunoassay was the other potentially controversial item in the rule change. There were some comments on this which were addressed.
- 3. The items in this rule change were chosen for being non-controversial items, the rest were left for another rule change. The Council requested to see the list of ideas for future rule changes.

#### III. Lab of the Year Award

- A. The Small Registered Lab of the Year Award went toDePere Wastewater Treatment Plant.
- B. The Large Registered Lab of the Year Award went toDairyland Power Cooperative. Their laboratory has been through significant improvements in the last few years.
- C. The Lab of the Year Award has been a positive experience for the Laboratory Certification and Registration Program. It has brought recognition to the laboratory community which has often been taken for granted or overlooked.

### IV. Amended Agenda Items

- A. The lack of internal communication between DNR Programs. (Council Chair's item)
  - The Council Chair and several Council members presented several examples of where some of
    the Departments programs had published documents or made requirements which had
    associated analytical problems. It was obvious to the Council that the other programs had not
    consulted with the Lab Certification Program to resolve these issues before releasing the
    guidance or making the requirements.
  - 2. The Council was concerned about the lack of internal communication between the Department's different programs and was inquiring as to what could be done to improve it. Mr. Sullivan acknowledged the problem and that it could be improved, but also stated several success stories where there was strong communication and cooperation between the Department's programs.
  - 3. Several ideas including a "document routing requirements" and consulting designated "area experts" were brought up by the Council.
  - 4. Mr. Sullivan committed to bringing this concern to the Department's attention.
  - 5. The Council will also write a letter to the Department stating its concern about the lack of internal communication and review process.

## V. National Laboratory Accreditation Program (NELAP)

- A. NELAC Meeting Update
  - 1. The NELAC third interim meeting handout was distributed and explained.
  - 2. Eighteen states have said that they will become NELAP accrediting authorities in the first round. As of 2/9/98, 20 applications have been received from potential NELAP accrediting authorities.\*
  - 3. The first labs are scheduled to be NELAP audited in 1999.
  - 4. For now, the State of Minnesota will not be in the first round and will only include commercial labs in NELAP.
  - 5. A prototype of a checklist for assessors will be available on the web site (http://134.67.104.12/html/nelac/nelac.htm).
  - 6. Sampling and field measurements may fall under NELAP accreditation.
  - 7. NELAC is working on the appeal rights of laboratories beyond the state level.
  - 8. States which apply to be NELAP accrediting authorities before July 1, 2000 will have a two

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year grace period to adopt legislation which would enable them to implement NELAP.

- B. NELAP Technical Advisory Committee (TAC)
  - An 18 member TAC has been assembled to advise the Department on whether or not to become a National Accrediting Authority and adopt the NELAC standards. The committee will also make recommendations on how to implement NELAP in Wisconsin. The members are as follows:

Ms. Barbara Burmeister Wisconsin State Laboratory of Hygiene
Ms. Diane Davis Wisconsin Power and Light - Edgewater
Mr. Dwight Easty Fort James - Neenah Tech. Center

Mr. Dean Falkner
Ms. Laura Forst
Wisconsin DATCP
Ms. Sheila Graham
Wisconsin DATCP
Mr. Paul Harris
Davy Laboratories
Mr. Paul Junio
NET - Watertown
Mr. Albert Kardoskee
DePere WWTP

Mr. DeWayne Kennedy-Parker Wisconsin State Laboratory of Hygiene

Mr. Craig Martin Wisconsin Electric Power Co. Mr. George Nelson UW - Stout Biology Dept.

Mr. Michael Ricker U.S. Oil Co., Inc.

Dr. William Sonzogni Wisconsin State Laboratory of Hygiene

Mr. Randall Thater Waukesha WWTP
Dr. David Turrfiff En Chem, Inc.
Mr. Gregory Zelinka Madison MSD

Mr. Paul Zovic Sigma Environmental Services

- 2. The TAC meetings will be facilitated by Ms. IsabelGutierrez and will have stringent timelines to come up with recommendations for the Department within 6 months.
- 3. The 1<sup>st</sup> of 6 meetings will be on Thursday, February 19, 1998.
- 4. After the introductory meeting, working committees and subcommittees will be formed.
- 5. Dr. Sonzogni suggested that the Departments legal services begin reviewing the statute. Mr. Sullivan agreed and committed to initiate a legal review of the statute.

### VI. Future Meeting Date

- A. The next Certification Standards Review Council meeting was tentatively set for Thursday, May 21, 1998.
- B. The program will work with the Chair to set up the next meeting. The Council members should contact the Chair or Vice-chair to get items on the next meeting's agenda.
- C. A motion was made to adjourn by the Council Chair, it was seconded by MsCawley and unanimously accepted.

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